UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	Oral Argument Requested

DEFENDANTS' REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF JOINT MOTION TO EXCLUDE THE OPINIONS OF KALIOPI PANAGOS, PHARM.D., R.Ph.

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INTRODUCTION

Once again, the opinions proffered by Plaintiffs' expert, Kaliopi Panagos, Pharm.D., R.Ph., warrant exclusion pursuant to Rule 702 due to a lack of support, her lack of qualifications to render them, and her improper foray into regulatory and legal conclusions. In an attempt to salvage Dr. Panagos's opinions, Plaintiffs resort to two unconvincing approaches: one, pointing broadly and blindly to her general experience in the pharmaceutical industry; and two, recharacterizing her opinions. Neither approach carries the day. Dr. Panagos's opinions remain inadmissible.

First, Plaintiffs have failed to demonstrate the reliability of Dr. Panagos's opinions. Specifically, Dr. Panagos fails to identify the bases for several of her opinions or even confirm information essential to her opinions. Plaintiffs' attempts to explain away faults in Dr. Panagos's methodology and their wholesale reliance on her (largely irrelevant) experience to support her opinions cannot save them.

Second, Dr. Panagos's general experience as a pharmacist and benefits consultant does not, without more, qualify her as an expert in FDA and regulatory matters, Medication Guides, the information upon which TPPs rely when placing a generic drug on a formulary or reimbursing for its purchase, or the process for including a drug in the Orange Book. Plaintiffs simply have not established that Dr. Panagos has the necessary specialized knowledge to render those opinions.

Third, Dr. Panagos has proffered several regulatory and legal conclusions,

which are not appropriate subjects of expert testimony. Plaintiffs deny that Dr. Panagos's opinions reach the ultimate issues in this case, but her report and deposition testimony show otherwise. Plaintiffs also fail to show that substituting "warranty" in Dr. Panagos's already excluded opinions with "assurance" and "representation" renders those opinions admissible.

Finally, plaintiffs cannot refute that Dr. Panagos failed to properly disclose an opinion about whether ZHP complied with regulatory standards.

For these reasons, those stated in Defendants' Motion ("Mot.") [ECF 2294], and those set out in this Court's ruling on Class Certification Expert Reports ("Class Cert. Ruling") [ECF 2261], Dr. Panagos's opinions should be excluded.

ARGUMENT

I. DR. PANAGOS'S OPINIONS ARE UNRELIABLE.

An expert opinion is reliable if supported by "good grounds." *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 321 (3d Cir. 2003) (citation and internal quotation marks omitted). Dr. Panagos lacks "good grounds" for several of her opinions, despite Plaintiffs' effort to mask her lack of support by talking up her experience and retooling her opinions.[1]

First, Plaintiffs' reframing of Dr. Panagos's opinions concerning the alleged

[1] Plaintiffs accuse Defendants of mischaracterizing Dr. Panagos's opinions, even though the Motion directly quotes several of them. (*See* Mot. at 9, 15–16, 21–22.)

presence of NDMA and/or NDEA in VCDs and the supposed effect on the "equivalence" between VCDs and the RLD fails. Plaintiffs argue that those opinions do not refer to a specific brand-name RLD, but rather "the RLD manufacturers' FDA applications and related documentation," which do not mention nitrosamines. (Opp. at 4–5.) Accordingly, Plaintiffs assert that what matters—and what Dr. Panagos is truly opining—is that the generic VCDs' ANDAs "never identified nitrosamines as an ingredient or as part of the manufacturing process," and not "whether a specific RLD pill may have contained nitrosamines." (*Id*. at 5.)

Plaintiffs' contention is inherently illogical: given that neither the VCDs' ANDAs ***nor*** the RLDs' NDAs list nitrosamines, then the actual presence of nitrosamines in the RLD pills does matter, under plaintiffs' theory, to Dr. Panagos's opinions that "the generic products could not have been equivalent to the RLD due to the presence of contaminants within the generic product."[2] (Mot. Ex. A ¶ 106.) (Especially since we know that the presence of nitrosamines, at least to some permissible limit, are allowable by FDA in these products whether listed or not.) Additionally, this Court has already precluded Dr. Panagos from opining that the alleged presence of impurities in VCDs rendered them no longer equivalent to the

[2] Dr. Panagos never looked at testing of VCDs for nitrosamines, relying instead of the voluntary recalls as evidence of impurities, which is not equivalent to reliance "on testing done by others." (*See* Opp. at 5 n.4 (inaccurately referring to the recall as "FDA's recall").)

RLD. [ECF 2261 at 94; Mot. Ex. D at 1-2 (showing that paragraphs 80, 102, 105, V, and IX of Dr. Panagos's 10/31/22 Report ("Report") are substantially the same as the excluded opinions); Opp. at 6 (presenting paragraphs 80, 102, 105, V, and IX of the Report as permissible opinions).][3] Plaintiffs' argument is no more than an attempt to disguise previously excluded opinions.

Second, with respect to Dr. Panagos's opinions concerning the formulary decisions of SummaCare and Emblem, Plaintiffs reveal that Dr. Panagos will ***not*** be opining on the formulary decisions of SummaCare and Emblem specifically.[4] (Opp. at 6.) Given this concession, this Court should exclude Dr. Panagos's opinions on that topic. (Mot. Ex. A at ¶¶ 20, 27, 30, 31, VIII, XIV.)[5]

Third, Plaintiffs fail to rebut the assertion that Dr. Panagos's opinions on the ANDA approval process and generic drug manufacturers' regulatory duties are unsupported. Not only does Dr. Panagos fail to cite a single FDA regulation in her

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[3] Plaintiffs incorrectly contend that only opinions concluding that bioequivalence was part of a "warranty" were excluded. [*See* ECF 2261 at 94 (excluding paragraphs 59 and D of Dr. Panagos's Class Certification Expert Report ("Class Report")); Mot. Ex. C ¶¶ 59 and D (making no mention of "warranty").]

[4] As set forth in the Motion, Plaintiffs' concession also renders Dr. Panagos's opinions on formulary inclusion and reimbursement by TPPs other than SummaCare and EmblemHealth irrelevant and a poor "fit" to this case. (Mot. at 11 n.5.)

[5] Plaintiffs' cited authority, concerning qualification and legal conclusion—not reliability—challenges, is inapposite. *New York City Transit Auth. v. Express Scripts, Inc.*, 588 F. Supp. 3d 424, 444 (S.D.N.Y. 2022); *Bradley v. S.C. Boys, Inc.*, Case No. 4:20-CV-00262, 2022 U.S. Dist. LEXIS 135644, at *6 (M.D. Pa. July 29, 2022); *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, MDL No. 2445, 2020 U.S. Dist. LEXIS 219949, at *153 (E.D. Pa. Nov. 24, 2020).

Report or testimony (*see* Mot. Ex. A; Mot. Ex. B at 94:23-95:10), she also explicitly stated that both "regulations for ANDA submission" and details of the ANDA process were "outside the scope" of her opinions. (*Id*. at 95:6-10, 120:18-121:8.) Plaintiffs' sole response—after venturing into discussions of fit and legal conclusions—fails to persuade. In attempting to provide the basis for paragraph 46 of the Report (which Defendants noted cites to an FDA webpage that lacks any discussion of the subjects within that paragraph), Plaintiffs do no more than point to Dr. Panagos's empty claim that the webpage supports her opinion.[6] This does not suffice to support an expert opinion.

Likewise, rather than demonstrating the reliability of Dr. Panagos's Medication Guide opinions, Plaintiffs make the puzzling argument that although the FDA does not require Medication Guides for VCDs, VCD manufacturers should have provided them anyway, and therefore Dr. Panagos's opinions are reliable. (Opp. at 10.) The fact of the matter is that the FDA does not require Medication Guides for VCDs; thus, any VCD-related Medication Guide opinions are both unreliable and unhelpful. Plaintiffs confirm as much, citing Dr. Panagos's testimony revealing that her Medication Guide opinions are propped up not by any factual

[6] This Court has already rejected several of Dr. Panagos's FDA regulatory opinions. [ECF 2261 at 94 (rejecting Class Report ¶¶ 52, 53, 59, D); Mot. Ex. D at 1–2.]

basis, but by her own personal beliefs and "expectations." (Opp. at 11 n.12.)[7]

Finally, several of Dr. Panagos's opinions are unreliable because they lack any reference to or explanation of supporting facts and because the citations that ***are*** included in the Report often fail to support the proffered opinion. (Mot. at 20–22.) In response, Plaintiffs cite caselaw to the effect that a "lack of copious citations [does not] render[] an opinion unreliable." (Opp. at 13 (quoting *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig*., MDL No. 2327, 2016 U.S. Dist. LEXIS 119174, at *3 (S.D.W. Va. Sept. 1, 2016)).) The problem with Dr. Panagos's Report is not a "lack of copious citations," but the presence of hardly any (*compare* Report (containing 13 footnotes in a 133-paragraph report), *with In re Ethicon Inc*., 2016 U.S. Dist. LEXIS 119174, at *11-12 (noting that the challenged report contained "a few particular opinions that are not accompanied by citations")), in contravention of Plaintiffs' duty to demonstrate that Dr. Panagos has "good grounds for . . . her belief[s]," *Calhoun*, 350 F.3d at 321.

Plaintiffs attempt to explain away the lack of support provided for Dr. Panagos's opinions by arguing that it is to be expected because they are based on her experience. (Opp. at 11.) Not so. "If the witness is relying solely or primarily on

[7] Any opinion that Medication Guides ***should have*** been provided for VCDs is improper. (*See* Mot. at 18 n.8 ("[A] generic drug manufacturer would not be able to add a Medication Guide unless it is part of the FDA-approved labeling for the RLD.") (citing *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011)).)

experience, then the witness must ***explain*** how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." Fed. R. Evid. 702, Advisory Committee Notes (2000) (emphasis added). Dr. Panagos has not explained how her general experience as a pharmacist and a benefits consultant amounts to the "extensive and specialized experience" needed to opine on the equivalence of drugs, the formulary decision-making of two TPPs for which she has not worked and whose pertinent documents she has not reviewed, or FDA regulatory requirements that she admittedly considers beyond the scope of her report and/or acknowledges are inapplicable. *Compare* Report *with Hendricks v. Ford Motor Co*., Case No. 4:12-cv-71, 2012 U.S. Dist. LEXIS 190785, at *5 (E.D. Tex. Sept. 6, 2012) (admitting an opinion on a car jack's failure rendered by expert with more than 20 years of "experience in failure analysis in mechanical metallurgical engineering"); *United States v. Lawson*, Case No. 3:08-CR-21-DCR, 2009 U.S. Dist. LEXIS 131083, at *12-15 (E.D. Ky. Apr. 13, 2009) (permitting an auditor with ten years of experience to opine, *inter alia*, on the "corporate and financial implications of documents"); *Fox v. Makarchuk*, Case No. 19-CV-207-J, 2021 U.S. Dist. LEXIS 179954, at *11-12 (D. Wyo. May 11, 2021) (permitting a doctor who contributed to "guidelines for apportionment under a worker's compensation system and . . . works frequently in devising systems for determination of fair apportionment" to "assign percentage

allocations to the cause of [plaintiff's] injuries").

In sum, Plaintiffs' attempt to dilute the Rule 702 standard should be rejected, and Dr. Panagos's challenged opinions should be excluded as unreliable.

II. DR. PANAGOS REMAINS UNQUALIFIED TO RENDER HER OPINIONS.

Plaintiffs also contend that Dr. Panagos's education and experience as a pharmacist and a benefits consultant qualify her to opine on FDA-related issues, the information TPPs rely on for formulary inclusion and reimbursement, and Orange Book inclusion because Dr. Panagos need not have "prior expertise working in [a] precise field" in order to "be an expert in that specific and narrow field." (Opp. at 14.) This argument, too, should be rejected.

"[T]he criteria required to qualify an expert turn largely upon ***the subject matter of the particular opinion to be offered***." *Kerrigan v. Maxon Indus.*, 223 F. Supp. 2d 626, 635 (E.D. Pa. 2002) (emphasis added); *see also Brugler v. Unum Grp.*, Case No. 4:15-cv-01031, 2019 U.S. Dist. LEXIS 158503, at *34–35 (D.N.J. 2019) ("The Third Circuit has held that a potential expert witness must possess 'sufficient knowledge' of a given subject in order to testify as an expert on that subject." (citation omitted)). For this reason, courts within this circuit have excluded the opinion that a machine's "back-up alarm was insufficient to alert crew workers because of the phenomenon of habituation" where the engineering expert lacked training or experience on the phenomenon and did not design or test (only ensured

proper mounting and wiring of) back-up alarms, *Surace v. Caterpillar, Inc.*, 111 F.3d 1039, 1055–56 (3d Cir. 1997), and have held that "experience in heavy truck maintenance and repair generally does not qualify [a proposed expert] to testify about a proposed safety design that would be connected to the truck's hydraulic functions" if he "lacks the necessary experience in designing and engineering hydraulic systems and safety devices intended to check the hydraulic operation," *Kerrigan*, 223 F. Supp. 2d at 639.

At bottom, Dr. Panagos's general experience in the pharmaceutical field does not qualify her to opine specifically on FDA-related issues, having never consulted for the FDA, a pharmaceutical company, or a medical device company, having never studied FDA regulatory issues more generally, and having never been involved with putting together, submitting, or reviewing an ANDA. (*See* Mot. at 24–25.) Nor does it qualify her to opine specifically on how a drug is included in the Orange Book, having never been involved with that decision. (*Id.* at 26–27.)[8] It likewise does not

[8] Plaintiffs' attempt to smooth out the contradiction between Dr. Panagos's testimony (that "if there was a deviation from therapeutic equivalence, the drug would absolutely not be in the Orange Book") and the Orange Book's own language (that inclusion of a drug therein "is independent of any current regulatory action being taken administratively or judicially against a drug product") fails. (Opp. at 18–19.) According to the FDA, "[t]he main criterion for the inclusion of any product [in the Orange Book] is that the product is the subject of an application with an approval that has not been withdrawn for safety or effectiveness reasons." Orange Book Preface, https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface (last visited Apr. 16, 2023). Dr. Panagos ignores this.

qualify her to opine on how TPPs and P&T committees create drug formularies and reimburse for purchases, given her limited experience doing that. (*Id*. at 25–26.)

Even accepting Plaintiffs' assertion that Dr. Panagos need not "have obtained her expertise in a certain manner" (Opp. at 16), she must still ***have*** that expertise, *Brugler*, 2019 U.S. Dist. LEXIS 158503, at *34-35 (noting that an expert "must possess 'sufficient knowledge' of a given subject in order to testify as an expert on that subject" (citation omitted)).[9] Dr. Panagos does not. Accordingly, her opinions on FDA-related issues, the information TPPs rely on for formulary inclusion and reimbursement, and Orange Book inclusion should be excluded.

III. DR. PANAGOS'S IMPERMISSIBLE LEGAL CONCLUSIONS MUST BE EXCLUDED.

Throughout her Report, Dr. Panagos renders several opinions that directly address "whether Defendant[s] w[ere] in regulatory compliance with the FDA," *Stanley v. Novartis Pharms. Corp*., Case No. 11-03191, 2014 U.S. Dist. LEXIS 198861, at *10 (C.D. Cal. May 6, 2014), and that "merely tell the jury what result to reach," *Peroza-Benitez v. Smith*, Case No. 17-3980, 2019 U.S. Dist. LEXIS 130012, at *3 (E.D. Pa. Aug. 2, 2019). Such opinions are impermissible legal conclusions,

[9] Plaintiffs' contention that Defendants' challenges go to the weight of Dr. Panagos's opinions puts the cart before the horse: "***Once the trial court has determined that a witness is competent to testify as an expert***, challenges to the expert's skill or knowledge go to the weight to be accorded the expert testimony rather than to its admissibility." (Opp. at 19 (emphasis added) (citation omitted).)

no matter how Plaintiffs try to reframe them.

A. Several of Dr. Panagos's "Opinions" are Improper Legal Conclusions.

In their Motion, Defendants quoted verbatim several of Dr. Panagos's opinions that clearly reveal her belief that Defendants failed to comply with FDA statutory and/or regulatory requirements. (Mot. at 28–29.) For instance, Defendants challenge Dr. Panagos's opinions that "[t]he contaminated VCDs were inconsistent with the ANDAs submitted for approval" (Mot. Ex. A at ¶ 108), and "[t]he presence of the carcinogenic contaminants was a clear and significant deviation from the required manufacturer compliance and obligation to safety" (*id.* at ¶ II).

Plaintiffs try in vain to frame such opinions as "stop[ping] short of . . . opining on whether the defendant has complied with [certain] duties." (Opp. at 20 (citation omitted).) The challenged opinions do no such thing and instead very much opine on Defendants' compliance with FDA requirements. (*See, e.g.*, Mot. Ex. A at ¶ II, *supra*; *see also Orner v. Nat'l Beef Packaging Co., LLC*, Case No. 4:13-cv-0837, 2015 U.S. Dist. LEXIS 164771, at *22-23 (M.D. Pa. Dec. 9, 2015) (holding that an expert "may testify to those facts that bear upon the ultimate issue but may not state any blunt legal conclusion as to whether [defendant] violated . . . the [statute]"); *In re Tylenol (Acetaminophen) Mktg., Sales Practices, & Prods. Liab. Litig.*, MDL No. 2436, 2016 U.S. Dist. LEXIS 98858, at *8–9 (E.D. Pa. July 27, 2016) (barring an expert opinion on "whether acetaminophen would be considered Generally

Recognized as Safe and Effective . . . under 21 C.F.R. § 330.10").)

Likewise, the Motion quotes verbatim several opinions where Dr. Panagos reaches the ultimate legal issue, essentially telling the jury how to rule. (Mot. at 29–30.) For instance, Dr. Panagos opines that "the representations made by [Defendants] were false," and "TPPs paid for medications they should not have paid for" (Mot. Ex. A at ¶ 103), and that Defendants "did not indicate that NDMA or NDEA were in their products in the package insert, in the medication guide, or on the prescription label," which "represents a misrepresentation of their product" (*id*. at ¶ 133). Plaintiffs do not, and cannot, demonstrate how these opinions—in a case involving claims of negligent misrepresentation and unjust enrichment—do not "tell the jury what result to reach." *Peroza-Benitez*, 2019 U.S. Dist. LEXIS 130012, at *3; *see also Krys v. Aaron*, 112 F. Supp. 3d 181, 192 (D.N.J. 2015) (holding that expert opinion that defendants "committed fraud, breaches of their fiduciary duties, and conversion" "unquestionably . . . render[ed] a legal opinion concerning whether various agents . . . complied with their obligations under federal securities law").

Moreover, this Court has already excluded several of the challenged opinions. (*See* Mot. Ex. D at 1–2; Mot. at 28–31.) Yet, Plaintiffs try to slip some opinions back in, arguing that they are merely "useful background information about how things work generally in the pharmaceutical industry and what categories of information P&T committees rely on when making decisions about the placement of drugs on

formularies." (Opp. at 21; *see also id*. at 21, 23 (urging admission of ¶ 99, 104, I, IV, V, and IX, which are substantially similar to excluded paragraphs 55, 58, B, D, and H of the Class Report).)

They are not. Instead, they opine directly on regulatory compliance (*see, e.g*., Mot. Ex. A at ¶ V ("[G]eneric manufacturers ***are not meeting the obligations required by the regulations***; the changed product ***cannot be deemed safe or effective*** and ***equivalence is nulled***; and the generic manufacturer ***may no longer rely on the RLD***.") (emphasis added)), or on essential elements of a cause of action (*id*. at ¶ IX ("TPPs ***reimbursed*** for these VCDs ***based on the assurances provided*** by the manufacturer in seeking approval and marketing the generics under the approved ANDA.") (emphasis added).) As such, Dr. Panagos's opinions are impermissible and excludable. (Mot. Ex. A ¶¶ 80, 99, 102–05, 106, 108, 133, II, V, IX, XII, XIV.)

B. Dr. Panagos's "Assurance" and "Representation" Based Opinions Are Synonymous With and Therefore Excludable Like Her "Warranty" Based Opinions.

In its Class Cert. Ruling, this Court excluded, as "a legal question to be posed to, and answered by, the factfinder," "Dr. Panagos's opinion as to TE codes serving as a mfr's warranty." [ECF 2261 at 94; *see also id*. (excluding also ¶¶ 47, 55-58, B, H, and I of the Class Report).] Plaintiffs seek to evade that ruling by pointing to Dr. Panagos's substitution of the term "warranty" with "assurance" and "representation." This wording change cannot transform Dr. Panagos's opinions

from improper legal conclusions into permissible expert opinions. (Mot. at 22.)

In *Patrick v. Moorman*, 536 F. App'x 255, 258 (3d Cir. 2013), the Third Circuit upheld the exclusion of a police expert's testimony where he "essentially opined that [the defendant's] actions were unreasonable and about what a reasonable officer would have done" because "[i]n a § 1983 suit, 'reasonableness' is practically interchangeable with 'excessiveness', so [the expert] might as well have opined that [the defendant's] use of force was excessive." Likewise, Dr. Panagos's "assurance" and "representation" opinions are "essentially" the "warranty" opinions that this Court has already excluded.[10] Plaintiffs have no response to this argument, which was unequivocally raised in the Motion. (Mot. at 32 n.14.) Accordingly, this Court should, once again, exclude Dr. Panagos's "warranty" based opinions. (Mot. Ex. A ¶¶ 80, 81, 84, 102, 103, I, IX, X, XIV.)

IV. DR. PANAGOS MAY NOT OFFER OPINIONS ABOUT ZHP NOT DISCLOSED IN HER REPORT.

The only reference to ZHP in Dr. Panagos's report states that "VCDs were manufactured, distributed, or sold by active pharmaceutical ingredient and finished dose manufacturers, including . . . Zhejiang Huahai Pharmaceuticals ('ZHP')." (Opp. at 25 (quoting Report ¶ 20).) Putting aside that this statement is factually

[10] Dr. Panagos confirmed as much. (Mot. Ex. B at 140:23–24 (as used in the Report, "assurance or warranty, they really mean the same thing"); *id*. at 141:5–7 ("[W]hether it's warranty or assurance, it really denotes . . . the same thing.").)

incorrect (ZHP did not manufacture, distribute, or sell any finished-dose VCDs), such a generalized reference obviously did not disclose an opinion about ZHP's conduct, its regulatory compliance, or whether its API was adulterated at the time of sale. Dr. Panagos admitted as much at her deposition, unequivocally stating that "***API manufacturers were not within the scope of my report here***." (Mot. Ex. B at 195:8-12 (emphasis added)). While Plaintiffs claim that defense counsel "confused" Dr. Panagos at her deposition, there is no evidence this is the case. It was not until Plaintiffs' counsel made speaking objections that Dr. Panagos began to change her story and assert that she intended to offer adulteration opinions with respect to ZHP's API that appear nowhere in her report. (*Id*. at 195:13-196:20, 197:22-198:14, 199:15-23.) Plaintiffs also fail to cite any authority supporting their argument that Dr. Panagos disclosed an opinion that ZHP's API was adulterated by including the FDA's November 29, 2018 Warning Letter to ZHP—which references adulteration—on the list of materials she reviewed. (Opp. at 25–26.) The law is clear that an expert must disclose her opinions in her report and provide reliable support for them. *See, e.g.*, *Krys*, 112 F. Supp. 3d at 207. Dr. Panagos did neither here.

CONCLUSION

For these reasons, and those discussed in the Motion, Defendants respectfully request that the Court grant Defendants' Joint Motion to Exclude the Opinions of Dr. Kaliopi Panagos.

Dated: April 25, 2023

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CERTIFICATE OF SERVICE

I, Steven M. Harkins, an attorney, hereby certify that on April 25, 2023, I caused a copy of the foregoing document to be served on all counsel of record via CM/ECF.

/s/ Steven M. Harkins
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